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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/752,899	12/29/2000	Frank J. Bunick	MCP-0262	9623

7590 12/02/2003

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EXAMINER
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EVANS, CHARESSE L

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 12/02/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/752,899

Applicant(s)

BUNICK

Examiner

Charesse L. Evans

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Action Summary*

Acknowledgement is made of the receipt of applicant's amendment and remarks filed September 16, 2003.

Claims 1-5 and 7-13 are pending in this Action.

### *Response to Arguments*

Applicant's arguments filed September 16, 2003, have been fully considered but are not persuasive. Applicant argues that one of the differences between the cited prior art references and the claimed invention is that the claimed invention requires the use of directly compressible dextrose monohydrate. The cited reference teaches this limitation. Please refer to column 13, Example XIII, where it describes that the agglomerate, including the active ingredient, was directly compressed. The referenced agglomerates were made from a liquid binder solution of materials and carbohydrate particles which include materials such as dextrose monohydrate (column 9, lines 5-8). Thus, this portion of the reference reads on applicant's claim.

Additionally, applicant appears to argue that the role of Valentine's sucrose as a binder is completely different than the role of sucralose in the claimed invention,

which is a sweetener. Examiner disagrees with applicant's position. The presence of the sucrose or sucralose is all that is needed to render obvious applicant's claim. In a composition, patentable weight is not given to the reason or purpose for including a component, as long as all of the necessary components are present. Furthermore, when a component is included in a composition, all of its properties and advantages are inherent to the composition. Therefore, the fact that applicants are claiming sucrose or sucralose as a sweetener rather than as a binder has no patentable weight.

Finally, applicant argues that the claimed sucralose is not comparable to the sucrose that is taught in the Valentine prior art reference. Examiner disagrees with this assertion. Both sucrose and sucralose are sweeteners and it would be an obvious variation to substitute sucrose for sucralose, as sucrose is the starting material for sucralose. Liu (WO 99/47126, page 13, line 15) was cited to demonstrate the interchangeability of the two substances. Despite, however, the suggestion that sucrose and sucralose can be interchangeable, and as described in the preceding paragraph, in claims to compositions, patentable weight is not given to the reason for including a component within a claimed composition. The fact that applicants are claiming sucrose or sucralose as a sweetener rather than as a binder has no patentable weight.

In the alternative, if applicant is arguing the criticality of utilizing sucralose rather than sucrose within the claimed composition, applicant is invited to present

data demonstrating such criticality and the unexpected results obtained that would be attributable to the use of sucralose.

The rejection is maintained.

### *Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charesse L. Evans whose telephone number is

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703-308-6400. The examiner can normally be reached on Monday - Thursday 7:00a - 4:30p; Alternating Fridays 7:00a - 3:30p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Charesse Evans  
Examiner  
Art Unit: 1615

November 17, 2003

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600